

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION**

)
) **MDL No. 1456**
) **Master File No. 01- 12257-PBS**
) **Subcategory Case. No. 06-11337**
)

THIS DOCUMENT RELATES TO:

) **Hon. Patti B. Saris**
)

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc., et al. v. Dey, Inc., et al.,*
Civil Action No. 05-11084-PBS

) **Magistrate Judge**
) **Marianne B. Bowler**
)
)

**DEY'S SUR-REPLY IN OPPOSITION TO UNITED STATES'
MOTION TO EXCLUDE CERTAIN OPINIONS OF W. DAVID BRADFORD, PH.D.**

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey") hereby submit their sur-reply in opposition to the United States' Motion to Exclude Certain Opinions of W. David Bradford, Ph.D.

The role of the court in a *Daubert* motion is to serve as a gatekeeper. Here, there is no question that Dr. Bradford's opinions are not the type of speculative junk science that *Daubert* is designed to keep out. To the contrary, the economic methods employed by Dr. Bradford have not been challenged by the Plaintiffs. In fact, Dr. Bradford pointed out numerous errors in the methodology of Plaintiffs' damages expert, Dr. Duggan, which Dr. Duggan later accepted. The Plaintiffs' motion focuses on the types of issues that are more properly addressed at trial. At that time, after Plaintiffs have had the opportunity to present their case-in-chief and after the Court and jury will have heard from Plaintiffs' experts, Dr. Bradford will present some of his opinions, including his opinions on generic competition and pricing (which have not been challenged by the Plaintiffs) and his critiques of Dr. Duggan's failure to consider dispensing costs in Dr. Duggan's but-for damages world. These opinions relate to key issues that have already been

identified by this Court as relevant and important, and should not be excluded. There is no need for any *Daubert* hearing, a request only made by the Plaintiffs in their reply, because there is no issue over Dr. Bradford's underlying methodology. Indeed, the entire motion is premature and should be denied.

I. DR. BRADFORD'S OPINIONS ARE PROPERLY EVALUATED IN THE CONTEXT OF TRIAL

The Plaintiffs' piecemeal motion is premature and asks the Court to attempt to parse opinions which need to be heard in a trial context. In a *Daubert* challenge, the role of the Court is as the gatekeeper:

“we emphasize that the court's gatekeeping function focuses on an examination of the expert's methodology. The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or, where appropriate, on summary judgment. *See Daubert*, 509 U.S. at 595, 113 S.Ct. 2786 (“The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.”); *Walker*, 208 F.3d at 587 (stating that when addressing whether expert testimony is reliable the district court should not consider the “factual underpinnings” of the testimony but should determine whether “[i]t was appropriate for [the expert] to rely on the test that he administered and upon the sources of information which he employed”)”

Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000) (reversing exclusion of expert witnesses and remanding for new trial). Here, however, the Plaintiffs have not critiqued the methodology or the expertise of Dr. Bradford. Rather, the Plaintiffs have improperly asked the Court to evaluate the factual underpinnings of selected parts of Dr. Bradford's analysis and the correctness of several of his conclusions on issues such as dispensing fees. These types of issues, even if shaky, which Dr. Bradford's are not, are properly left for cross-examination. “Exclusion of expert testimony is the exception rather than the rule because vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof

are the traditional and appropriate means of attacking shaky but admissible evidence.”

McGonigal v. Sears Roebuck & Co., Civil Action No. 07-CV-4115, 2009 WL 712345, at*5 (E.D. Pa. March 13, 2009) (internal citations omitted); *see also Taylor, Bean, & Whitaker Mortgage Corp. v. GMAC Mortgage Corp.*, No. 5:05-cv-260-Oc-GRJ, 2008 WL 3819752, at *5 (M.D. Fl. Aug. 12, 2008).

The extreme step of exclusion of those of Dr. Bradford’s opinions that have been highlighted by the Plaintiffs in their motion is especially unwarranted here, where his opinions must be considered in the context of this complex case. The Plaintiffs’ motion has misrepresented and mischaracterized Dr. Bradford’s opinions by isolating them from the totality of his economic opinion and from the facts and evidence that will be put before a jury. In order to decide this motion, the Court needs context for those opinions that will actually be offered at trial after hearing from Plaintiffs’ experts and from the other witnesses. The best place for this context is the trial itself, and at that time, if there remain any issues, they can be addressed.

Furthermore, the Plaintiffs raise for the first time in their reply that they “expect[] to object to and seek to exclude many additional opinions or statements of Dr. Bradford” at trial. *See* Plaintiffs’ Reply, fn1. This is a concession that Dr. Bradford will testify at trial and an implicit recognition of the piecemeal approach of the Plaintiffs’ motion.

II. DR. BRADFORD’S MEDICARE OPINIONS ARE ADMISSIBLE

Despite the Plaintiffs’ attempts to isolate particular opinions, charts, and figures, Dr. Bradford’s opinions cannot be evaluated in a vacuum. Dr. Bradford’s opinions on WAC, cross-subsidization and dispensing fees in the Medicare context are relevant and admissible to the key issues that have already been identified by the Court. The evidence Dey will present at trial will show that access to care was a requirement in both Medicare and Medicaid, and that dispensing costs were always a part of the reimbursement formula that required consideration, both prior to

and after the passage of the MMA and that CMS understood and acknowledged these realities. Dr. Bradford's opinions quantify these factors in a way that was not done by Dr. Duggan. These opinions are admissible, relevant, and should not be excluded by the Court.

Medicare must reimburse its providers enough to maintain access for its beneficiaries, and CMS was concerned about access to care. (Neimann 11/19/09 Tr., Exhibit 2 to Reid Decl., at 604:10-14). Dey will show at trial that Medicare officials knew that if Medicare reimbursed at actual acquisition costs, their concerns about access would require an increased dispensing fee. The record shows that when Congress or CMS contemplated reducing the ingredient cost portion of the reimbursement equation, they simultaneously proposed an increased dispensing fee. Thus, in December 1995, when CMS contemplated moving by regulation from AWP to actual acquisition cost ("AAC"), they proposed adding a dispensing fee to account for the services provided by the pharmacy. Mr. Robert Neimann, a former policy analyst who CMS employees described as the Medicare payment policy expert during the relevant period, testified as to the draft regulation:

Q. Would you agree with me that that addition of a dispensing fee was intended to account for the loss of margin to these providers in going from an AWP system to an AAC system?

THE WITNESS: Yes. I think that's right.

(*Id.* at 284:17-22). Again, in 1998, President Clinton's budget included a proposal to reimburse for prescription drugs under Medicare based on AAC plus a dispensing fee. Mr. Neimann testified about this proposed change:

Q. As you read the summary here of Section 11236, does that -- can you tell me if that seems to you, from memory, to be an accurate description of the 1998 budget proposal?

A. Yes.

Q. And the very last sentence indicates that pharmacies would be given a dispensing fee in addition to their acquisition cost, correct?

A. In the last paragraph of which?

Q. The last sentence of the last paragraph?

A. Oh, yes.

Q. That indicates, am I correct, that a dispensing fee would be allowed to pharmacies in addition to their acquisition costs?

A. Yes, it does.

Q. And that would have the same purpose as we discussed earlier in going from AWP to AAC, correct?

A. Yes. I think so.

Q. And this is something that you would think that you probably wrote?

A. It's the kind of thing I would have written.

(Neimann 9/14/07 Tr., Exhibit 1 to Reid Decl., at 297:09 - 298:08). Finally, when Congress passed the MMA and ingredient cost reimbursement decreased to ASP, the dispensing fee for the inhalation drugs at issue here increased from \$5 to \$57, later leveling at \$33, where it remains to this day.

Dr. Bradford's opinions dovetail with the factual record, while the Plaintiffs' expert, Dr. Duggan, failed to consider it at all. Dr. Duggan calculates his "damages" or "differences" without taking into account the fact that Medicare reimbursement has two components: ingredient cost and dispensing fee. Dr. Bradford quantifies what Dr. Duggan ignored and critiques Dr. Duggan's decision not to examine dispensing fees in his damage calculations.

In their reply, the Plaintiffs abandon the position that the dispensing fee issues raised by Dr. Bradford are not relevant to the issue of damages. *See* Plaintiffs' Reply at 7. The Plaintiffs' remaining critique, therefore, is that Dr. Bradford's opinions are based on studies and evidence

that are outside the relevant time period and are therefore speculative. However, as the Court has commented, Dr. Bradford is using these figures and evidence as a proxy. This is not improper under any *Daubert* standard. It should be noted that while Dr. Duggan has not calculated damages past Q4 2003, the Amended Complaint sets forth the relevant time period as “[f]rom on or before December 31, 1992, and continuing through 2004 in the case of the Medicare program”. See Dkt. 5614 at paragraph 50 (emphasis added). Therefore, the Plaintiffs’ complaints about the 2004 dispensing cost studies are misplaced, as 2004 is a part of the “relevant” time period under their pleading.

Furthermore, and more importantly, Dr. Bradford’s opinions resulting from his analysis of what actually happened as a result of the studies and evidence regarding the MMA’s dispensing fee changes are not speculative: it is reality. With the enactment of the MMA, Congress lowered ingredient cost reimbursement to 106% of ASP, and in doing so, acted comparably to Dr. Duggan who, in calculating his differences, lowers ingredient cost reimbursement to his calculated average price. However, at the same time, Congress dramatically increased the dispensing fees for Dey’s inhalation drugs, ultimately using a dispensing fee of \$33 where it remains to this day. Dr. Duggan does not change the dispensing fee in his analysis, but rather holds it constant at \$5. Dr. Bradford disagrees with Dr. Duggan’s damages analysis, and opines that there is a dispensing fee shortfall which decreases the amount of differences or damages calculated by Dr. Duggan. In forming these opinions regarding the dispensing costs for inhalation drugs, a necessary component of the Medicare reimbursement formula, Dr. Bradford does not pull numbers out of the air. Instead, relying on his experience and expertise as a health care economist and his review of the record, he looked to the actual studies that calculated actual dispensing fee costs for the exact drugs at issue here and, for some

of his opinions, he uses the dispensing fee used under the MMA as a proxy for the dispensing fee that should have been used by Dr. Duggan. At trial, he can be cross-examined on these choices and his opinions. The \$33 dispensing fee implemented under the MMA is the result of empirical studies and back and forth dialogue. It would be improper for Dr. Bradford to ignore these studies and the factual record which show what actually happened when a system similar to that proposed by Dr. Duggan was implemented. These opinions of Dr. Bradford are key to rebutting Dr. Duggan's "but-for" analysis.

The Plaintiffs devote pages to evidence that they believe demonstrates that Dr. Bradford's opinions are wrong. However, these are factual points for cross-examination and not arguments that he has employed improper methodology or made errors in his calculations. The Plaintiffs' disagreement with Dr. Bradford's ultimate conclusions is not a basis for a *Daubert* motion.

Furthermore, the Plaintiffs' reliance on *Ward v. Dixie Nat'l Life Ins. Co.*, 595 F.3d 164 (4th Cir. 2010) is puzzling as that case does not even involve a *Daubert* motion. *Ward* involved a breach of an insurance contract, not an FCA claim, and the court's analysis hinges on the benefit of the bargain concept of contract law. While the court accepted an argument other than that put forth by defendants' expert, the court did not exclude the expert's testimony. Indeed, the case does not address a *Daubert* or in limine motion made by one party to exclude the use of the other party's expert. In fact, the court does not address the validity, reliability, or anything else about the defendants' expert in *Ward*. Therefore, contrary to the Plaintiffs' argument here, *Ward* does nothing to shed light on a court's gate-keeping function.¹

¹ The Plaintiffs also cite to two cases for the standard of proof required for an expert, however, these cases are not on point. Plaintiffs' reliance on *Moberly v. Sec'y of Health and Human Servs.*, 592 F.3d 1315 (Fed. Cir. 2010) for the idea that the "more likely than not" standard requires proof that meets the "preponderance of evidence" standard is factually distinguishable and beside the point. The case was brought under the National

The Plaintiffs also devote several pages to mischaracterizing Dr. Bradford's opinions as ones that opine on Congressional action or inaction. His opinions recount what actually occurred with regard to these drugs including, for example, Congress's refusal in 1999 to allow CMS to use "inherent reasonableness" to lower the ingredient cost reimbursement for albuterol sulfate or CMS' own refusal to use the 2000 DOJ AWP's in the Medicare program. Dr. Bradford does not attribute any motive to Congress or CMS: he examines the factual record because it informs his view of what policymakers were indeed performing their function. Similarly, Dr. Bradford critiques Dr. Duggan's average price Medicare arrays by substituting Dey's published WAC to demonstrate that the reimbursement level was set to maintain access and that Dey, in publishing its actual wholesale list price, as well as knowing the other price points in the market, had no reason to think that Medicare had set reimbursement except at the level it deemed appropriate, let alone that it was causing false claims to be paid by Medicare to providers. Finally, Dr. Bradford's WAC analysis also demonstrates that Dr. Duggan, through his damage calculations, has essentially calculated another version of Dey's reported WAC.

Childhood Vaccine Injury Act by a mother on behalf of her daughter and alleged that a vaccine had caused her daughter's seizure disorder. The plaintiff appealed an unfavorable ruling by the special master on two grounds, one of which was that the special master erroneously applied a heightened standard of proof rather than the preponderance of evidence standard required under the Vaccine Act. This has no bearing on the instant case. Moberly was brought under a different statute that provided for a particular standard of proof. Thus, Plaintiff's attempt to rely on Moberly is entirely misguided. *Natchitoches Parish Hosp. Serv. Dist. v. Tyco Int'l, Ltd.*, 262 F.R.D. 58 (D. Mass. 2008) was an antitrust action in which plaintiffs sought class certification. The court granted plaintiffs' motion. The language quoted by Plaintiff – regarding when and how the burden of production and proof moves to defendant – is in the context of the Court's discussion on when injury to competition can be inferred as a matter of general antitrust law. 262 F.R.D. at 70. It has nothing to do with liability under the FCA or admissibility of expert testimony.

III. DR. BRADFORD'S MEDICAID OPINIONS ARE ADMISSIBLE

This Court has granted the Plaintiffs' motion to bifurcate, and has set the Medicare-only portion of this case for trial on September 13, 2010. Therefore, as the Plaintiffs acknowledge in their reply, the Court need not reach Dr. Bradford's Medicaid opinions at this time. *See* Plaintiffs' Reply at page 14, fn15. The portions of the briefing filed by the parties relating solely to Medicaid are contained in pages 13-25 of the Plaintiffs' moving brief, Dkt. 6194, pages 15-24 of Dey's opposition, Dkt. 6985, and pages 14-19 of the Plaintiffs' reply, Dkt. 7055. The Court should defer ruling on this issues until the Medicaid-only trial is scheduled. In the interests of not burdening the Court with unnecessary briefing, Dey will file its sur-reply on the Medicaid issues if and when such a trial is scheduled, assuming Plaintiffs decide to proceed with the motion at that time.

IV. THIS COURT SHOULD DENY THE PLAINTIFFS' REQUEST FOR AN EVIDENTIARY HEARING

The Plaintiffs did not request a evidentiary hearing when they filed their motion, but have included a request for a *Daubert* hearing in their reply papers. As is amply clear, there is no reason for holding such a hearing. The issues raised by the Plaintiffs do not implicate the methodology employed by Dr. Bradford, and the proper time for the Court to deal with the Plaintiffs' objections is in the context of trial after Plaintiffs' experts, including Dr. Duggan, have testified, or during voir dire.

CONCLUSION

For the reasons set forth herein, this Court should deny the United States' Motion to Exclude Certain Opinions of W. David Bradford, Ph.D.

Dated: May 7, 2010

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on May 7, 2010, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ Sarah L. Reid
Sarah L. Reid